DEC 2 7 2013

K130895

**510(k) Summary**

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| Proprietary Name: | ReUnion RSA Shoulder System |
| Common Name: | Shoulder Prosthesis |
| Classification Name and Reference: | Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3660 |
| Regulatory Class: | Class II |
| Product Codes: | KWS |
| For Information contact: | Estela Celi, Regulatory Affairs Specialist<br>Stryker Trauma AG<br>325 Corporate Drive<br>Mahwah, NJ 07430<br>Phone: (201) 831-6461 Fax: (201) 831-3461<br>estela.celi@stryker.com |
| Alternate Contact: | Karen Ariemma<br>Howmedica Osteonics Corp.<br>325 Corporate Drive<br>Mahwah, NJ 07430<br>Phone: (201) 831-5718 Fax: (201) 831-4718<br>karen.ariemma@stryker.com |
| Date Prepared: | March 28, 2013 |

Legally Marketed Device to Which Substantial Equivalence is Claimed:

- K080642 & K072804-Comprehensive Reverse Shoulder (Biomet)
- K112069- Reverse Shoulder System (DJO Encore)
- K081171-Tritanium Acetabular Shell (Howmedica Osteonics)
- K062250-Delta Xtend Reverse Shoulder System (DePuy)
- K021478-Delta Shoulder (DePuy)

**Description:**

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the ReUnion RSA Shoulder System. The ReUnion RSA Shoulder System is a system of components intended for total shoulder replacement in a reverse shoulder configuration. The system is comprised of a Humeral Cup, Humeral Insert, Glenoid Baseplate, Center Screw, Peripheral Screws and Glenosphere. The Humeral Cup with the Humeral Insert are attached to

the humeral side of the joint via the ReUnion TSA Humeral Stem while the Glenosphere is implanted with the Glenoid Baseplate onto the glenoid side of the joint fixated with locking Center and Peripheral Screws. The ReUnion RSA Shoulder System components are indicated for primary reverse shoulder or revision reverse shoulder replacement procedures having gross rotator cuff deficiency.

**Intended Use:**

The ReUnion RSA Shoulder System is intended for primary, fracture, or revision total shoulder replacement. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implant(s).

**Indications:**

The ReUnion RSA Shoulder System in intended for primary, fracture, or revision total shoulder replacement. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implant(s).

- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis or rheumatoid arthritis
- Proximal humeral fracture
- Revision of previously failed shoulder joint replacement
- Glenoid Baseplate components are intended for cementless use with the addition of screw fixation. The humeral stem components are intended for both cemented and cementless use.

**Summary of Technologies:**

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices. The following differences exist between the subject and predicate devices.

- Both the Reverse Shoulder System and the ReUnion RSA Shoulder System subject device contain two taper junctions. The Comprehensive Reverse Shoulder contains an additional taper present in the taper adaptor between the Glenosphere and Glenoid Baseplate.
- The Comprehensive Reverse Shoulder contains a post as well as Center Screw to fix the Glenoid Baseplate to the glenoid bone. Both the ReUnion RSA Shoulder System and the Reverse Shoulder System contain only a Center Screw.

**Non-Clinical Testing:**
Non-clinical laboratory testing was performed for the ReUnion RSA Shoulder System components to determine substantial equivalence. Testing and evaluations demonstrated that the subject device is substantially equivalent to devices currently cleared for marketing. The testing/analysis included the following:

- Fatigue Strength Testing
- Micromotion Testing
- Engineering, Literature, and MAUDE Analysis of Fretting in the Shoulder Joint
- Glenoid Baseplate Substrate and Coating Characterization
- Static Testing of the humeral Insert/humeral cup junction
- Disassembly testing of the glenosphere/glenoid baseplate connection.
- Evaluation of Range of Motion

**Clinical Testing:** Clinical testing was not required for this submission.

**Conclusion:** The ReUnion RSA Shoulder System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 27, 2013

Stryker Corporation
Howmedica Osteonics Corporation
Ms. Estela Celi
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K130895
Trade/Device Name: ReUnion RSA Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: November 15, 2013
Received: November 18, 2013

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K130895

Device Name: ReUnion RSA Shoulder System

Indications for Use:
The ReUnion RSA Shoulder System is intended for primary, fracture, or revision total shoulder replacement. The patient's joint must have gross rotator cuff deficiency, a functional deltoid muscle and be anatomically and structurally suited to receive the selected implant(s).

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. [illegible]
Division of [illegible] Devices